ject, applicable to both single and multi-company projects. Any obligatory internal processes should be completed in tandem. **RESULTS:** Health outcomes studies, pharmacoeconomic evaluations, and risk sharing agreements for the access of new pharmaceuticals were identified as projects of high priority to implement in the following years. **CONCLUSIONS:** The steps outlined in this guidance, although not compulsory, will provide useful practical tips for how to go about setting up a Joint Working project in Catalonia (Spain), and to assist through the remainder of it. This guide is not a substitute for suitable regulatory or legal advice.

**PHP201**

**MAPPING AND ANALYSING PHARMACEUTICAL POLICY SETTINGS WORLDWIDE**

Maniadakis N[1], Kourlaba G[2], Shen J[3], Holtorf AP[4], Kalo Z[5]

[1]*National School of Public Health, Athens, Greece,* [2]*National and Kapodistrian University of Athens School of Medicine, Athens, Greece,* [3]*Abbott, Basel, Switzerland,* [4]*Health Outcomes Strategies LLC, Basel, Switzerland,* [5]*Syreon Research Institute, Budapest, Hungary*

**OBJECTIVES:** In the context of increasing demand and expenditure for health services it is important to elaborate policies which maximise efficiency. Pharmaceuticals account for about a fifth of total health care expenditure and are often target of health care efficiency policies. The aim of this study is to classify and grade pharmaceutical supply and demand control policies across the globe and cluster systems by regulatory rigidity. **METHODS:** Pharmaceutical policies and market data across 65 countries were researched in the literature with emphasis on pricing, reimbursement, dispensing, expenditure and demand control domains. Policies were classified by domains and graded through a multi-country expert survey for the degree of regulation. Cluster analysis helped to group countries by policy types. **RESULTS:** Pricing policies for on-patent products (with increasing degree of regulation) include: free pricing, direct negotiations, value-based-pricing, cost-plus-pricing, conditional-pricing, reference-pricing, state dictates and tenders. Cost control policies include: discounts, rebates, risk-sharing agreements, price-volume agreements, profit controls, pay-backs, claw-backs, margin cuts, price cuts, freezes, and tenders. Reimbursement policies include: variants of ATC5-based internal referencing, variants of statutory copayments, and variants of ATC4-based internal referencing. Dispensing policies were: no restrictions, indicative substitution, mandated or compulsory substitution. Demand controls include: educational campaigns, prescription aids, indicative prescription guidelines, indicative INN prescription, prescription monitoring, quotas, targets, predefined budgets, compulsory INN prescription, mandatory electronic prescription, compulsory prescription guidelines, prior/posterior approvals, sanctions and incentives for target/guidelines adherence. Cluster analysis identified a set of countries using an intermediate regulation policy approach and another with a more rigid approach. These did not differ significantly (p: 0.20) concerning pharmaceutical expenditure as % of GDP. **CONCLUSIONS:** A variety of policies were used in recent years for controlling pharmaceutical expenditures. Countries fall into two subsets based on the intensity of the regulation. More regulated systems do not appear to be associated with lower pharmaceutical expenditure.

**PHP202**

**THE COST-EFFECTIVENESS OF PERIODIC SAFETY UPDATE REPORTS (PSURS) FOR BIOLOGICALS IN EUROPE**

Bouvy J[1], Ebbers H[2], Schellekens H[2], Koopmanschap MA[3]

[1]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [2]*Utrecht University, Utrecht, The Netherlands,* [3]*Erasmus University, Rotterdam, The Netherlands*

**OBJECTIVES:** The safety profile of new drugs is usually not fully established upon market entry, giving cause for Europe's comprehensive pharmacovigilance system. A key regulatory vehicle to communicate the outcomes of pharmacovigilance activities is the Periodic Safety Update Report (PSUR), which summarizes a product's worldwide safety data and facilitates periodic assessment of its benefit-risk profile. We assessed the cost-effectiveness of all PSURs submitted in Europe during 1995-2009 for biologicals, using a societal perspective. **METHODS:** We evaluated two regulatory scenarios: Full Regulation (pharmacovigilance including PSURs) and Limited Regulation (pharmacovigilance without PSURs). We assessed the source of regulatory action for all urgent safety issues that were identified for biologicals during 1995-2009. In two out of 24 urgent safety issues (systemic spread of botulinum toxin and edema after use of dibotermin-alfa), PSURs were the regulatory instrument that identified the safety issue and we assumed these issues would have been discovered five years later under limited regulation. Estimates from the literature and Markov-chain life tables were used to calculate costs and effects of PSURs for biologicals. **RESULTS:** The incremental cost-effectiveness ratio (ICER) of Full Regulation versus Limited Regulation was €342,110 per quality-adjusted life year gained. Extensive sensitivity analyses indicated a low probability of the Full Regulation scenario being cost-effective. Only two parameters resulted in a more favorable ICER: a 100% risk reduction after identification of the urgent safety issues (base-case assumption was 25%) and a high risk (1 in 1,000 patients) of severe systemic spread after therapeutic use of botulinum toxin (base-case assumption 1 in 10,000 patients). **CONCLUSIONS:** Regulatory cost-effectiveness analysis is a feasible instrument for assessing the (added) value of parts of the drug regulatory framework. In light of high costs of regulatory compliance, cost-effectiveness should be a consideration in deciding whether or not safety-related regulatory actions are required.

**PHP203**

**UTILIZATION OF THE HUNGARIAN PUBLICLY FINANCED HEALTH CARE SYSTEM BY THIRD (NON EU) COUNTRY CITIZENS**

Kovács G[1], Boncz I[2], Gyeney L[3]

[1]*Széchenyi István University, Győr, Hungary,* [2]*University of Pécs, Pécs, Hungary,* [3]*Pázmány Péter Catholic University, Budapest, Hungary*

**OBJECTIVES:** The number of citizens from third countries (outside of European Union or stateless) permanently living in Hungary is 205 000, and annually ca. 23000 people get permit to settle. Current study aims at exploring what group of foreigners, when and for what type of service use publicly financed health care. **METHODS:** Data was retrieved from National Health Insurance Fund Administration of Hungary (*NHIFA*) and Central Statistical Office. Current study's base was processing the last five years' statistical data (2007-2012), concerning health care of third country citizens permanently living in Hungary. We analyzed the volume, place and medical specialty of these services. **RESULTS:** In the last 5 years third country citizens required inpatient care 9414 times (61% in Budapest), emergency care 11776 times (63% in Budapest), out-patient care 72306 times (57% in Budapest). Patient accessed health care providers due to medical problems in the following medical fields: obstetrics (19%), surgery (18%), laboratory (18%), pediatrics (7%), and ophthalmology (6%). Most of the patients are from Ukraine (42 %), China (22 %), Vietnam (11 %), ex-Yugoslavia (6 %) and Russia (6 %). Analysis by nationalities shows that Chinese population requires health care relatively few times (for instance, 2011: 5%, in 2012: 6%) and even these are almost exclusively done in Budapest. In contrast USA citizens see doctors relatively often (2011: 8%, 2012: 8%), mainly in relation to diagnostics and curative surgery. From the neighboring non-EU states (23095 people, 31%) Ukrainian and (5709 people, 7%) ex-Yugoslavian citizens needed health care in the investigated period. Despite previous expectations, need for health care is not the characteristics of border regions but the capital city. **CONCLUSIONS:** Utilization of the Hungarian publicly financed health care system is significant by third country citizens. When planning health care capacity, this crucial fact must be taken into consideration.

**PHP204**

**PHARMACEUTICAL REGULATION IN EUROPE AND ITS IMPACT ON CORPORATE R&D**

Mahlich J[1], Eger S[2]

[1]*University of Vienna, Vienna, Austria,* [2]*Medical University of Vienna, Vienna, Austria*

**OBJECTIVES:** Many European countries regulate drug prices in order to cope with rising health expenditures. On the other hand, price regulation distorts incentives to invest in pharmaceutical R&D. This study aims at empirically assessing the impact of price regulation on pharmaceutical R&D expenditures. **METHODS:** We analyze a sample of 20 leading pharmaceutical companies between 2000 and 2008. The share of sales in Europe serves as a proxy for the degree of price regulation. We control for other determinants of R&D such as cash flow, company size, leverage ratio, growth rate, and Tobin's q. **RESULTS:** Our results suggest a nonlinear relationship between European sales ratio and R&D intensity. Beyond a threshold of 33% of sales generated in Europe, a higher presence in Europe is associated with lower R&D investments. **CONCLUSIONS:** Price regulation has a negative impact on pharmaceutical R&D investments. Policy makers must take long term effects of regulation into account.

**PHP205**

**ELICITING THE RELATIVE IMPORTANCE OF KEY ELEMENTS FOR BENEFIT-RISK ASSESSMENT: A COMPARISON AMONG GENERAL POPULATION, HEALTH AUTHORITY AND MEDICAL DOCTORS**

Ha JH[1], Na HS[1], Chung MW[1], Byun JH[2], Kwon SH[2], Park EJ[3], Lee EK[2]

[1]*Ministry of Food and Drug Safety, Chungcheongbuk-do, South Korea,* [2]*Sungkyunkwan University, Suwon, South Korea,* [3]*Korea Institute for Health and Social Affairs, Seoul, South Korea*

**OBJECTIVES:** This research was designed to find out the key attribute for benefit-risk assessment using swing weight method in general population, health authority and hospital doctors. **METHODS:** We selected six important elements for each benefit and risk assessment based on previous study. The elements of benefit assessment consisted of disease severity, size of population affected by disease, clinical guidelines recommendation, comparative interventions limitation, improvement of efficacy/effectiveness, improvement of quality of life. The attributes of risk assessment contained overall incidence of adverse events, overall incidence of serious adverse events, discontinuation rate due to adverse events, drug or food interactions, drugs of potential misuse, risk management. 583 subjects constituted 3 groups (general population, health authority and hospital doctors) were selected across the country by quota sampling method and performed survey to evaluate preference of each elements with the swing methods repeatedly. The trained interviewers assisted participant successfully completed survey. **RESULTS:** Improvement of efficacy/effectiveness and overall incidence of serious adverse events were revealed as the most important attributes than others for benefit- risk assessment in all three groups. Health authority group outweighed the improvement of efficacy/effectiveness [Mean (±SD): 0.208(±0.04)] and overall incidence of serious adverse events [Mean (±SD): 0.220(±0.05)], while 0.204(±0.03), 0.216(±0.04) in doctor group and 0.197(±0.04), 0.185(±0.04) in general population respectively. In six benefit attributes, the lowest preference score was clinical guidelines recommendation [0.114(±0.04)] in health authority group and [0.144(±0.04)] in general population while size of population affected by disease [0.126(±0.04)] in hospital doctor group. Among six risk elements, the lowest preference was drugs of potential misuse showed in health authority [0.117(±0.04)] and in hospital doctors [0.121(±0.04)] while risk management [0.121(±0.04)] in general population. **CONCLUSIONS:** This shows that improvement of efficacy/effectiveness among benefit attributes and overall incidence of serious adverse events among risk attributes are key elements for benefit-risk assessment.

## HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

**PHP206**

**COVERAGE WITH EVIDENCE DEVELOPMENT IN SWEDEN – FORMALITY OR EFFECTIVE WAY TO REDUCE UNCERTAINTY?**

Kornfeld A[1], Schroeder M[2], Toumi M[3]

[1]*Creativ-Ceutical, Paris, France,* [2]*Creativ-Ceutical, Copenhagen, Denmark,* [3]*University Claude Bernard Lyon 1, Lyon, France*

**OBJECTIVES:** TLV (formerly LFN) is responsible for reimbursement decisions in Sweden. They regularly give temporary reimbursement with request for additional

data: Coverage with Evidence Development (CED). The objective of this study was to review the outcomes of the CEDs granted by TLV during the years 2005 to 2012, and to appreciate if it is an effective way to manage uncertainty. **METHODS:** All decisions published from January 2005 to December 2012 on the TLV website were screened. All decisions that included a CED were reviewed and the information on the initial decision for a CED and the final decision based on the evidence developed were extracted in a standardized way. The information was then analyzed. **RESULTS:** During the period TLV issued 38 decisions with a CED, 4 in 2012, 5 in 2011, 11 in 2010, 3 in 2009, 2in 2008, 8 in 2007, 5 in 2006 and none in 2005. For 10 CEDs issued 2010 to 2012 the time for evaluation had to yet been reached. For 12 CED decision taken from 2006 to 2010 the time for evaluation was reached but no decision had been taken and the products continue to be reimbursed according to the conditions in the temporary reimbursement decision. 7 products were granted general reimbursement and 9 limited reimbursement based on the evaluation of the evidence. No product was rejected reimbursement. **CONCLUSIONS:** Although it is early to draw any final conclusions, a significant number of CED decisions were not followed up with a final decision, which leads to continued reimbursement. The risk of de-reimbursement based on a CED seems minimal in Sweden. Therefore it is unclear if CED will actually contribute to manage uncertainty in Sweden.

**PHP207**

**VARIANCES IN INDIVIDUALS' PRESCRIPTION DRUG COSTS IN IRELAND**

Walshe V[1], Kenneally M[2], Buckley G[2]
[1]*Health Service Executive, Cork, Ireland,* [2]*University College Cork, Cork, Ireland*

**OBJECTIVES:** To assess the average individual's drug costs prescribed under the main community drug scheme in Ireland over time, by age cohort and by geographical region. It also examined regional costs having standardized for age and sex. **METHODS:** The 2002 to 2012 average pharmacy payment per eligible person, number of items prescribed per person and the average cost per item prescribed were calculated. The most recent average individual cost of medicines was examined for each of the 4 health regions and 32 sub-regions by 22 age and sex cohorts. Regional age and sex adjustments were made by applying the scheme's national age and sex weights to each region's costs. This produced regional cost estimates independent of age and sex variations. **RESULTS:** Community drug expenditure has undergone substantial growth in the past 10 years with costs more than doubling and the number of persons covered by the main scheme increasing by nearly 60%. Nationally an individual's average cost of medicines was €713 in 2011, varying from €670 (-6%) in HSE-West to €762 (+7%) in HSE-South. Sub-regional LHO (local health office) cost variances were significantly greater ranging from €200 to €1,200. Average cost increases with age and for persons over 75 was nearly 4 times those aged 35 to 44 (€1,689 versus €446). Removing the impact of age and sex increases cost variances marginally overall, restraining some regions costs and promoting others. **CONCLUSIONS:** Individuals' prescription drug costs vary significantly by age and sex however regional cost differences are not explained by variances in age and sex and may be a result of other factors such as prevalence of chronic health conditions and GP prescribing patterns.

**PHP208**

**ANALYSIS AND CLASSIFICATION OF RISK-SHARING SCHEMES PROPOSED IN REIMBURSEMENT APPLICATION RECEIVED BY AHTAPOL IN 2012**

Zawodnik S[1], Iwanczuk T[1], Hermanowski T[2], Matusewicz W[3]
[1]*Agency for Health Technology Assessment in Poland, Warsaw, Poland,* [2]*Department of Pharmacoeconomics, Medical University of Warsaw, Warsaw, Poland,* [3]*Agency for Health Technology Assessment in Poland (AOTM), Warsaw, Poland*

**OBJECTIVES:** To analyze and classify the Risk-Sharing Schemes (RSSs) proposed in reimbursement applications received by Agency for Health Technology Assessment in Poland (AHTAPol) in 2012. **METHODS:** Risk-Sharing Schemes proposed in reimbursement applications received by AHTAPol in 2012 were quantitatively and qualitatively analyzed. The classification of the RSSs was also conducted based on both Carlson's approach and the Polish Act on Reimbursement of medicinal products. **RESULTS:** In the studied period, 52 reimbursement applications with 26 proposed RSSs were received by AHTAPol. They were classified into 5 categories according to the Act on Reimbursement. The most common category was making the official sales price dependent on the applicant providing supplies at a reduced price, as specified in the negotiations on the price of the medicine (34.61%). Further categories were: making the official sales price dependent ona pay-back of a part of the reimbursement obtained to the entity which is obliged to finance benefits with public funds (23.08%), making the official sales price dependent on the level of turnover of the medicine (11.54%) and making the level of the applicant's revenues dependent on the health effects achieved (3.85%). RSSs classified as others constituted 26.92% of all. Among 26 proposed RSSs only 8 of them could be classified according to the Carlson's approach (1 proposition included more than one category). As a results, 4 Price Volume Agreements, 4 Manufacturer Funded Treatment Initiation and 1 Conditional Treatment Continuationwere identified. **CONCLUSIONS:** Most of the propositions should not be considered as RSS according to the Carlson's approach. The most common propositions were related to medicinal product's price reduction and did not include any risk sharing. There is a strong need for further research.

**PHP209**

**RISK SHARING FOR INNOVATIVE PHARMACEUTICALS WITHIN SOCIAL HEALTH INSURANCE: EXPERIENCES FROM CHINA**

Chen W[1], Zhang L[1], Fan W[2]
[1]*Fudan University, Shanghai, China,* [2]*School of Public Health, Fudan University, Shanghai, China*

**OBJECTIVES:** To understand current risk sharing scheme landscape for innovative pharmaceuticals in some typical provinces and cities of China. **METHODS:** Risk sharing schemes for pharmaceuticals in four provinces (Guangdong, Zhejiang, Jiangsu and Sichuan) and three cities (Guangzhou, Hangzhou and Chengdu) were systematically collected through visiting social health insurance bureau websites, literature review and key informant interview. Case study and comparison analysis were conducted among these schemes. **RESULTS:** Two kinds of risk sharing schemes, performance based scheme and financial based scheme, were employed in sampling provinces and cities, with the latter model more often implemented. Performance based scheme has only been developed in one city (Guangzhou) for a non-small-cell lung cancer drug. Patients eligible for inclusion criteria and treated in one of three designated hospitals could be qualified to reimburse for more than one year treatment if they were responsive to the drug. Other provinces and cities has adopted the financial based scheme, mainly focusing on increasing patients access to expensive drugs, usually for breast cancer, leukemia and non-small-cell lung cancer and not covered by health insurance schemes. For instance, local health insurance fund of Zhejiang and Jiangsu province would only reimburse patients' five to six months treatment and pharmaceutical company should sponsor patients' treatment for the next six months. Besides, cities like Qingdao and Chengdu implemented the price volume scheme for special drugs and medical materials in order to control fund expenditure. **CONCLUSIONS:** By risk sharing scheme, some innovative drugs, previously not covered by social health insurance, can be reimbursed, which will increase patients' access, reduce patients economic burden, and help expending pharmaceutical companies' market share. However, as risk sharing scheme in China has only been adopted for only one or two years, long-term impact still needs to be observed and evaluated.

**PHP210**

**SQUARING THE CIRCLE: INNOVATIVE CONTRACTING TO ACHIEVE MARKET ACCESS FOR INNOVATIVE PRODUCTS**

Street-Docherty LM, Morrison S
*GfK Bridgehead, Melton Mowbray, UK*

In an increasingly resource-constrained environment, a variety of innovative contracting arrangements exist, representing an alternative to conventional pricing and reimbursement agreements between payer and manufacturer. There are various tools and resources that may influence funding with which payers and prescribers would welcome support from manufacturers. **OBJECTIVES:** To gain an overview of contractual agreements currently used within the pharmaceutical sector and to uncover how innovative contracting has, and continues to, evolve. **METHODS:** Secondary research was conducted to identify examples of innovative contracting, highlighting elements that work and associated hurdles, in order to understand issues relating to transparency and implementation. **RESULTS:** Sixteen markets worldwide embrace innovative schemes with a further 5 markets beginning to show uptake. In the past, agreements were predominantly performance-based. However, companies are increasingly moving towards financial schemes such as product bundling, confidential discounts and fixed price treatments. The most common elements of risk-sharing agreements are price volume agreements (39%), requirement for data collection (29.5%), and access limited only to eligible patients (13.1%). Innovative contracts are predominantly used for drugs that relate to high cost or high performance with oncology being the therapeutic area that dominates these agreements. **CONCLUSIONS:** Innovative contracting schemes can aid manufacturers with market access, help to maintain price and increase usage. However, the current design of many agreements is suboptimal, and there are hurdles which need to be overcome. It is important that there is a balance between risk and incentive for all stakeholders, and this balance between the benefits and cost implications must be carefully considered.

## HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

**PHP211**

**THE HEALTH OF HEALTH TECHNOLOGY ASSESSMENT IN IRELAND: FIVE POINTS FOR IMPROVEMENT**

O'Mahony J[1], O'Neill C[2]
[1]*Trinity College Dublin, Dublin, Ireland,* [2]*National University of Ireland Galway, Galway City, Ireland*

This study critically appraises the contribution of cost-effectiveness analysis (CEA) in improving the rational allocation of health care resources in Ireland. While Ireland has successfully established some of the institutional infrastructure for CEA, there remain key areas for improvement: 1) Ireland has an explicit cost-effectiveness threshold of €45,000/QALY. It resulted from negotiations between the pharmaceutical industry and the public health service and only applies to pharmaceutical interventions. If Ireland is to use a threshold, it would be better served by an empirically determined threshold that applies to all interventions. 2) The threshold has recently been exceeded by a number of expensive drugs, in some cases by a very large margin. Conversely, despite being highly cost-effective, colorectal screening remains unimplemented due to a failure to allocate resources. In the absence of clarity around these decisions, the allocations appear to indicate that considerations of budget impact are dominating rather than complementing those of cost-effectiveness. 3) Recent CEAs by Ireland's statutory health technology assessment authority, the Health Information and Quality Authority (HIQA), appear to confuse average cost-effectiveness ratios with incremental cost-effectiveness ratios (ICERs). Clarity around the interpretation of cost-effectiveness evidence is required to instil confidence in the process. 4) Ireland has an established CEA process to appraise new drugs. However, this process has been bypassed in recent cases, as some costly cancer drugs have been approved before being subject to CEA, despite recommendations that these drugs be assessed. Consistency in approach is required to instil confidence in the process. (5) Greater transparency around reimbursement decisions would be desirable, whereby the relevant bodies issue documentation explaining their decisions and deliberations. In conclusion, CEA could make a greater contribution to rational resource allocation in Ireland if more rigorous and consistent decision rules were applied. Greater accountability of the decision making process should further that goal.